UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/673,643	10/31/00	YOKOI M	M&M-031-USA

HM12/0125

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EXAMINER	
GRUN, J	
ART UNIT	**PAPER NUMBER**
1641	4

DATE MAILED: 01/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/673,643	Applicant(s) YOKOI et al.
	Examiner James L. Grun, Ph.D.	Group Art Unit 1641

☒ Responsive to communication(s) filed on *31 Oct 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-11* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsperson will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors and should be carefully revised. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Particularly, the invention commensurate with that as instantly claimed.

Applicant desires an immunoassay reagent which, in use, results in agglutination of a solid phase and modification of signal generation by the steric inhibition of an enzyme inhibitor reaction with enzyme immobilized on the solid phase. However, absent further description and guidance from Applicant, one would not be assured of the ability to practice the invention as claimed with an enzyme substrate which is also sterically inhibited from interacting with enzyme on the agglutinated solid phase. Signal modification would not be related to the action of the enzyme inhibitor.

Moreover, one would not be assured of the ability to practice the invention with "plural different combinations in type of said antibody or antigen, enzyme and substrate" as instantly claimed if different antibody or antigen components were bound to the same carrier as disclosed. One would be unable to determine whether agglutination of such multi-component bound particles and the resultant signal modification were the result of different degrees of interaction of unknown sample ligand(s) with one of the components or to another of the components or to the plurality of components. Applicant only exemplifies standards in which concentrations of both ligands vary comparably in the same direction, i.e. more of both ligands in the standard results in more agglutination and more signal modification. It would be expected that standard curves for the individual ligands would overlap with the combination standard exemplified and that it would be impossible to ascribe any given signal modification to one or the other components interacting with any particular concentration of their respective ligands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 5, 6, and 9-11, "the quantitative determination" and "the activity" lack antecedent basis. As several antigen or antibody recitations appear in the claims and it is not clear what is corresponding, thus, for clarity "said" --target-- "antigen or antibody" should be recited at line 5 of claim 1.

In claim 2 it is not clear how the multiple reagents of the claim further limit "an immunoassay reagent" as claimed in the independent claim.

In claims 3 and 4, "said enzyme inhibitor" and "the quantitative determination" lack antecedent basis. As several antigen or antibody recitations appear in the claims and it is not clear what is corresponding, thus, for clarity "said" --target-- "antigen or antibody" should be recited at line 5 of claim 3.

In claim 4 it is not clear how the multiple reagents of the claim further limit "an immunoassay reagent" as claimed in the independent claim.

In claims 7 and 8, "the quantitative determination" lacks antecedent basis. As several antigen or antibody recitations appear in the claims and it is not clear what is corresponding, thus, for clarity "said" --target-- "antigen or antibody" should be recited at line 5 of claim 7.

In claim 8 it is not clear how the multiple reagents of the claim further limit "an immunoassay reagent" as claimed in the independent claim.

In claim 11, "the form" and "the degrees" lack antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kasahara et al (U.S. Pat. No. 4,582,792).

Claims 1-8 and 11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kasahara et al (U.S. Pat. No. 4,649,105).

Either of the Kasahara et al references teach similar reagents for measuring ligand. Ligand or anti-ligand and enzyme or enzyme inhibitor are immobilized on a solid phase, which can be different areas on the same polymer, two attached polymers, or two different polymer particle groups. The immobilized components are reacted with a conjugate comprising anti-ligand or ligand and enzyme inhibitor or enzyme and also with enzyme substrate. In instances taught by the reference in

which the ligand or anti-ligand and enzyme or enzyme inhibitor are immobilized on different polymer particles, the invention as instantly claimed is also anticipated during the use of the reagent of the reference and the binding of the conjugate thereto. Ferritin, containing iron, bound to the polymer of the references is considered herein as meeting the limitation as instantly claimed of the carrier containing a magnetic or magnetizable material.

Claims 7-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ashihara et al (U.S. Pat. No. 4,621,048).

Ashihara et al teach reagents for detecting ligand in a variety of embodiments comprising enzyme, enzyme substrate, and a conjugate of anti-ligand antibody bound to anti-enzyme. Components may be further bound to one or more macromolecular compound(s), however water-soluble compounds are preferred.

Claims 7-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Boguslaski et al (U.S. Pat. No. 4,134,792).

Boguslaski et al teach a reagent and method for specific binding assay using a conjugate of a binding component for target analyte and an enzyme modulator (see e.g. cols. 3-4). Binding of the conjugate to the corresponding target analyte in a homogeneous scheme causes a measurable change in the ability of the enzyme modulator label to affect the activity of an added enzyme on its substrate.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Kasahara et al (U.S. Pat. No. 4,582,792) or Kasahara et al (U.S. Pat. No. 4,649,105), in view of Ashihara et al (U.S. Pat. No. 4,621,048).

The teachings of the references of Kasahara et al are as set forth above and differ from the invention as instantly claimed in not specifically teaching anti-enzyme antibodies as the enzyme inhibitor and in not specifically teaching the use of magnetic or magnetizable, microorganism, or cell membrane fragment particles.

Ashihara et al teach anti-enzyme antibodies as enzyme inhibitors in immunoassays.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used anti-enzyme antibodies as enzyme inhibitors, as taught in Ashihara et al, in

the reagents and methods of the references of Kasahara et al because anti-enzyme antibodies were well known to the art as enzyme inhibitors and one would have had an extremely reasonable expectation that any known enzyme inhibitor would perform its expected function in the reagent and methods of the references of Kasahara et al, as modified, if the enzyme which the inhibitor was known to inhibit was involved in the reagent and methods. It would have been further obvious to have substituted any polymer or particle known for immobilization in immunoassays in the reagents and methods of the references of Kasahara et al, as modified, with the reasonable expectation that the known polymer or particle would perform its known and expected immobilization function.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ullman et al (U.S. Pat. No. 4,193,983) disclose colloidal particles having ligand and label individually covalently bonded thereto. The interaction between label and receptor provides a means for modulating signal, such as the use of an enzyme label with an enzyme inhibitor.

Ito et al (U.S. Pat. No.4,868,106) disclose labelled conjugates and immobilized binders and enzyme inhibitors for use in immunoassays.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., Technology Center 1600, Group 1640, Art Unit 1641, whose telephone number is (703) 308-3980. The Examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

James L. Grun, Ph.D.
January 22, 2001

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641